CHAPTER 3
SECTION 8.5

LIVER TRANSPLANTATION

Issue Date: September 3, 1986
Authority: 32 CFR 199.4(e)(5)(v)

I. PROCEDURE CODE RANGE

47133 - 47136 (ICD 9 CM - 50.51, 50.59)

II. POLICY

A. Depending upon the date of admission and the beneficiary residence, liver transplantation is subject to the requirements of the Specialized Treatment Service (STS) program. For these requirements, see OPM Part Two, Chapter 24.

1. Beneficiaries who reside in a liver transplant STS facility (STSF) catchment area and are in need of a liver transplantation, must be evaluated by that facility before receiving a liver transplantation. See OPM Part Two, Chapter 24, Section IV.

2. If the liver transplantation cannot be performed at an STSF, an STSF NAS (or an STSF authorization) will be issued, reference OPM Part Two, Chapter 24.

NOTE: For admissions on or after September 23, 1996, an STSF NAS is not required for TRICARE Prime enrollees even when these beneficiaries use the point of service (POS) option. For such admissions the enrollees are required to obtain an authorization from the Health Care Finder.

3. Effective September 23, 1996, if liver transplantation cannot be performed in an STSF for TRICARE Prime enrollees, such beneficiaries will be referred to the Health Care Finder for issuance of an authorization, reference OPM Part Two, Chapter 24.

B. For beneficiaries residing in a Managed Care Support (MCS) region, preauthorization for a liver transplantation is required in addition to the requirement for an STSF NAS.

1. A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the Health Care Finder (HCF) before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and HCF authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive health care services from non-network civilian providers without the required PCM referral and HCF authorization, MCS contractors shall reimburse charges for the services on a Point of Service basis. Special cost-sharing requirements apply to Point of Service claims. For specific information on Point

of Service cost-shares and catastrophic cap calculations, see Chapter 12, Section 2.2, Section 10.1 and Chapter 13, Section 14.1.

2. For Standard and Extra patients residing in an MCS region, preauthorization is the responsibility of the MCS Medical Director, Health Care Finder or other designated utilization staff.

C. Preauthorized benefits are allowed for living-related donor liver transplantation (LRDLT).

1. A TRICARE Prime enrollee must have a referral from his/her PCM and an authorization from the HCF before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and HCF authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive health care services from non-network civilian providers without the required PCM referral and HCF authorization, MCS contractors shall reimburse charges for the services on a Point of Service basis. Special cost-sharing requirements apply to Point of Service claims. For specific information on Point of Service cost-shares and catastrophic cap calculations, see Chapter 12, Section 2.2, Section 10.1 and Chapter 13, Section 14.1.

2. For Standard and Extra patients residing in an MCS region, preauthorization is the responsibility of the MCS Medical Director, Health Care Finder or other designated utilization staff.

3. For admissions prior to June 1, 1999, an STSF NAS is not required for LRDLTs. For admissions on or after June 1, 1999, an STSF NAS (or an STSF authorization) is required for LRDLT subject to the provisions in OPM Part Two, Chapter 24.

D. The designated preauthorizing authority shall only use the criteria contained in this policy when preauthorizing liver and LRDLTs.

E. Affirmative Patient Selection Criteria for Liver and LRDLT. Benefits may be allowed for medically necessary services and supplies related to liver and LRDLT when the transplantation is performed at a TRICARE or Medicare approved transplantation center for beneficiaries who:

1. Are suffering from irreversible hepatic disease; and

2. When the medical record documents that more conservative treatments have failed, and

3. Are approaching the terminal phase of their illness (e.g., death is imminent, irreversible damage to the central nervous system is inevitable, or the quality of life has deteriorated to unacceptable levels).

F. Liver and LRDLT transplants performed for beneficiaries suffering from irreversible hepatic disease resulting from hepatitis B or C is covered.

G. Benefits may be allowed for medically necessary services and supplies related to liver and LRDLTs for:

1. Evaluation of a potential candidate's suitability for liver transplantation whether or not the patient is ultimately accepted as a candidate for transplantation.

2. Pre- and post-transplantation inpatient hospital and outpatient services.

3. Pre- and postoperative services of the transplantation team.

4. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

5. The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

6. Blood and blood products.

7. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and generally accepted practice within the general medical community (i.e., proven).

8. Complications of the transplantation procedure, including inpatient care, management of infection and rejection episodes.

9. Periodic evaluation and assessment of the successfully transplanted patient.

H. Benefits may be allowed for Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

I. Benefits may be allowed for DNA-HLA tissue typing determining histocompatibility.

III. POLICY CONSIDERATIONS

A. For beneficiaries who reside in contractor regions, when there is any question as to whether the beneficiary meets the clinical criteria for a liver transplantation, the claim must be developed and referred to medical review for a determination of clinical eligibility.

B. Services and supplies that may be cost-shared are limited to those listed in 32 CFR 199.4(e)(5)(v)(C).

C. For beneficiaries who reside in TRICARE regions, preauthorization and retrospective authorization of liver or LRDLT must meet the following two requirements:

1. Patient meets (or as of the date of transplantation, would have met) patient selection criteria; and

2. Transplantation facility is (or as of the date of transplantation, would have been) TRICARE or Medicare approved for liver transplantation at the time of transplantation.

D. For beneficiaries who reside in TRICARE regions but fail to obtain preauthorization for liver or LRDLT, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority as outline in paragraph II.B. for liver transplantation and paragraph II.D. for LRDLT, under Policy, is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the transplantation. TRICARE Prime enrollees who failed to obtain preauthorization will be reimbursed only under Point of Service rules.

E. Benefits will only be allowed for transplantations performed at a TRICARE or Medicare approved liver transplantation center. The contractor in whose jurisdiction the center is located is the certifying authority for TRICARE authorization as a liver transplantation center. Refer to Chapter 11, Section 11.5 for organ transplantation certification center requirements.

F. Claims for services and supplies related to liver transplantation through September 30, 1998, will be reimbursed based on billed charges. Effective October 1, 1998, liver transplantation will be paid under the DRG. Acquisition costs related to the liver transplant will continue to be paid on a reasonable cost basis and not included in the DRG.

G. Claims for transportation of the donor organ and transplantation team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.

H. Benefits will be allowed for donor costs. Refer to Chapter 3, Section 1.6L for guidelines regarding donor costs associated with organ transplantations.

I. Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the TRICARE patient.

J. Acquisition and donor costs are not considered to be components of the services covered under the DRG. These cost must be billed separately on a standard UB-92 claim form in the name of the TRICARE patient.

K. Transportation of the patient by air ambulance may be cost-shared when determined to be medically necessary. Reference Chapter 7, Section 2.1.

L. For DoD beneficiaries who reside in a liver transplantation Specialized Treatment Service facility (STSF) catchment area, the issuance of an STSF NAS shall be in accordance with OPM Part Two, Chapter 24. For admissions prior to June 1, 1999, an STSF NAS is not required for LRDLT. For admissions on or after June 1, 1999, an STSF NAS (or STSF authorization) is required for LRDLT.

NOTE: Effective for admissions on or after September 23, 1996, an STSF NAS is not required for TRICARE Prime enrollees even when these beneficiaries use the POS option. For such admissions the enrollees are required to obtain an authorization from the Health Care Finder, reference OPM Part Two, Chapter 24.

M. When a properly preauthorized transplantation candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplantation from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

IV. EXCLUSIONS

Liver transplantation and LRDLT is excluded:

A. When any of the following contraindications exist:

1. Significant systemic or multisystemic disease (other than hepatorenal failure) which limits the possibility of full recovery and may compromise the function of the newly transplanted organs.

2. Active alcohol or other substance abuse.

a. Benefits may be allowed if:

(1) The patient has been abstinent for at least six months prior to the transplantation; and

(2) There is no evidence of other major organ debility (e.g., cardiomyopathy).

(3) There is evidence of ongoing participation in a social support group such as Alcoholics Anonymous; and

(4) There is evidence of a supportive family/social environment.

3. Malignancies metastasized to or extending beyond the margins of the liver; or,

4. Viral-induced liver disease when evidence of viremia is still present.

B. For:

1. Expenses waived by the transplantation center (e.g., beneficiary/sponsor not financially liable).

2. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

3. Administration of an unproven immunosuppressant drug that is not FDA approved or has not received TRICARE approval as an appropriate "off-label" drug indication. Refer to Chapter 7, Section 7.3 for Policy requirements for immunosuppression therapy.

4. Pre- or post-transplantation nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members).

5. Transportation of an organ donor.

C. Artificial assist devices. Assist devices are generally used for bridge to transplantation, until a suitable donor becomes available. Assist devices when used for bridge to transplantation are considered unproven.

D. Services, supplies or devices, even those used in lieu of the transplantation, when determined to be related or integral to an unproven procedure, may not be cost-shared (see Chapter 8, Section 14.1, for guidelines on determining coverage for related services).

V. EXCEPTIONS

A. Services and supplies for inpatient or outpatient services that are provided prior to and/or after discharge from hospitalization for a liver or LRDLT performed in an unauthorized TRICARE or Medicare liver transplantation center may be cost-shared subject to applicable Program policy. Preadmission services rendered by an unauthorized transplantation center may also be cost-shared subject to applicable program policies.

B. Aftercare related to a liver or LRDLT performed prior to July 1, 1983. Otherwise authorized services and supplies for transplantation related inpatient or outpatient services which are provided following discharge from hospitalization for a liver or a LRDLT performed prior to July 1, 1983, may be cost-shared subject to applicable program policy.

C. Liver or LRDLT performed on an emergency basis in an unauthorized liver transplantation facility may be cost shared only when the following conditions have been met:

1. The unauthorized center must consult with the nearest TRICARE-authorized liver transplantation center regarding the transplantation case;

2. It must be determined and documented by the transplantation team physician(s) at the authorized liver transplantation center that transfer of the patient (to the authorized liver transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate; and

3. All other TRICARE contractual requirements have been met.

VI. EFFECTIVE DATE July 1, 1983.

A. August 1, 1992, for LRDLT.

B. October 26, 1992, for removal of medical indications list.

C. For STSF NAS requirement, effective dates will be as indicated in the OPM Part Two, Chapter 24.

D. November 1, 1994, for hepatitis C.

E. December 1, 1996, for hepatitis B.

- END -